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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,325	02/27/2002	Jeffrey I. Weitz	GDV-001.01	6259

7590 01/14/2004

Millen, White, Zelano, & Branigan, P.C.
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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

17

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,325

Applicant(s)

WEITZ ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1 and 2 have been canceled. Claims 35, 54, and 62 have been amended. Claims 70-80 have been added. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 70-74 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites a molecular weight range of about 8,000 to about 12,000. The specification supports several molecular weight ranges, but the examiner does not find support for this particular range.

Claim Rejections - 35 USC § 103

Claims 35-69 are again rejected under 35 U.S.C. 103(a) as being unpatentable over HEPAR (EP 101141) in view of NIELSEN (US 5,106,734) as set forth in the previous Office action. Newly added claims 70-80 are included in this rejection.

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The invention is as set forth in the previous Office action. Newly added claims 70-80 recite MMWHs having molecular weight ranges of 8,000 to 12,000 (claim 70) and 8,000 to 10,000 (claim 75).

Applicant's arguments filed 26 September 2003 have been fully considered but they are not persuasive.

Applicant first contends that "[e]ven if one were to modify the Hepar disclosure to adjust for molecular weight as alleged, the resultant modified Hepar mixture would still lack the enriched pentasaccharide featured in the claims." However, there is no evidence supporting this allegation. As was discussed in the previous Office action, Applicant has acknowledged that the interaction of heparin with antithrombin is mediated by a unique pentasaccharide sequence. The fact that the Hepar products have increased antithrombotic activity, (See page 4, lines 1-19) appear to support pentasaccharide enrichment.

Applicant then argues that "[t]he harsh depolymerization method of Hepar provides desulfated heparin fragments" and "the final step in the Hepar process involves resulfation in an attempt to restore the sulphate groups that are essential for heparin's interaction with antithrombin." Again, Applicant provides no evidence to support the alleged desulfation. Furthermore, the examiner is unable to find the cited final resulfation step in the reference. However, with regard to a resulfation step, the reference does teach "the present invention [Hepar process – see page 4, lines 27-30] results in a low molecular weight heparin with the same advantageous ratio but *without the need for the sulphation step.*" (Emphasis added) Therefore, the further discussion of the criticality of 3-O-sulfation does not appear to be on point.

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With regard to Nielsen, Applicant argues that the reference relates to a method for obtaining a heparin product having a predetermined average molecular weight of about 6500. It appears that Applicant's argument is that the Nielsen method would be limited to providing a fraction of this molecular weight. The examiner respectfully disagrees with this characterization of the reference. The depolymerization reaction, as any chemical reaction, is time-dependent. See Table 1. Nielsen describes a spectrophotometric method for monitoring the reaction. Although the first data point reported by Nielsen is at 1 hr, ($M_N=6750$) it would clearly be within the scope of one of ordinary skill to employ this method to provide fractions throughout the molecular weight range taught by Hepar by using a reaction time of from less than 1 hr up to about 4.5 hr.

The newly submitted claims have molecular weight ranges that are also encompassed by the range taught by Hepar. It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare heparin products of any molecular weight range within that taught by Hepar. Applicant has not shown any criticality or unexpected results stemming from these molecular weight ranges that are somewhat narrower than those of the art.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

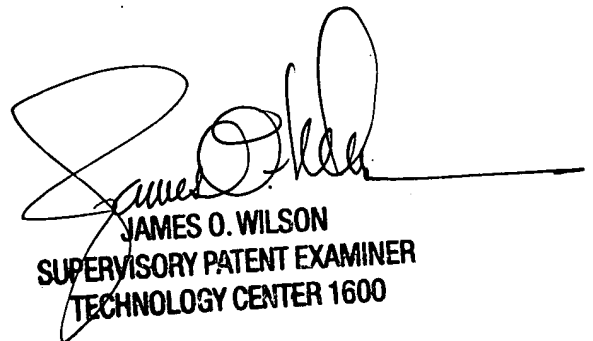
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
January 2, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600